

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT :	Dotan <i>et al.</i>	CONFIRMATION NO. :	7497
SERIAL NUMBER :	10/728,227	EXAMINER :	James Leslie Grun
FILING DATE :	December 3, 2003	ART UNIT :	1641
PATENT NO. :	7,592,150	ISSUE DATE :	September 22, 2009
FOR :	METHOD FOR DIAGNOSING DISEASES BASED ON LEVELS OF ANTI-GLYCAN ANTIBODIES		

Mail Stop: Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT
UNDER 37 C.F.R. §1.705(d)

The above-identified application issued on September 22, 2009. The total patent term adjustment calculated by the United States Patent and Trademark Office under 35 U.S.C. §154(b) is 412 days, which is recited on the face of the above-referenced patent. Applicants petition the U.S. Patent and Trademark Office for reconsideration of the patent term adjustment calculation to **815 days**, based on the facts provided herein. This Request is submitted in view of the decision by the U.S. District Court decision in *Wyeth v. Dudas* (D.D.C. 2008) on September 30, 2008.

This patent application was filed on December 3, 2003, and is therefore subject to the patent term adjustment procedures set forth in 37 C.F.R. §§ 1.702 to 1.705 for applications filed on or after May 29, 2000.

On March 18, 2004, the Office mailed a Notice to File Missing Parts of Non-Provisional Application.

On June 18, 2004, Applicants filed a Response to the Notice to File Missing Parts. This response was received by the Office within three-months of the mailing date of the action.

On September 22, 2006, the Office mailed a Restriction/Election-of-Species. The action was mailed 596 days after the fourteen month requirement for mailing of the first action after the

date on which the application was filed under 35 U.S.C. §111(a). As shown in Exhibit A, the number of days of Patent Term Adjustment accounts for the 596 day Office delay.

On October 20, 2006, Applicants filed a Response to Election-of-Species/Restriction. This response was received by the Office within three-months of the mailing date of the action.

On January 5, 2007, the Office mailed a Non-Final Office Action. This Action was mailed within the four months of the filing of the reply filed under 35 U.S.C. §132.

On April 5, 2007, Applicants filed a Response to the Non-Final Office Action. This response was received by the Office within three-months of the mailing date of the action.

On July 11, 2007, the Office mailed a Final Office Action. This Action was mailed within the four months of the filing of the reply filed under 35 U.S.C. §132.

On January 11, 2008, Applicants filed a Request for Continued Examination with a Petition for a three-month extension of time. This response was filed 92 days after the date that is three months after the mailing date of the Final Office Action. As shown in Exhibit A, the number of days of Patent Term Adjustment accounts for the 92 day Applicant delay.

On March 5, 2008, the Office mailed a Non-Final Office Action. This Action was mailed within the four months of the filing of the reply filed under 35 U.S.C. §132.

On September 5, 2008, Applicants filed a Response to the Non-Final Office Action with a Petition for a three-month extension of time. This response was filed 92 days after the date that is three months after the mailing date of the Final Office Action. As shown in Exhibit A, the number of days of Patent Term Adjustment accounts for the 92 day Applicant delay.

On December 23, 2008, the Office mailed a Non-Final Office Action. This Action was mailed within the four months of the filing of the reply filed under 35 U.S.C. §132.

On March 18, 2009, Applicants filed a Response to the Non-Final Office Action. This response was received by the Office within three-months of the mailing date of the action.

On March 31, 2009, the Office mailed the Notice of Allowance/Notice of Allowability, and the Determination of Patent Term Adjustment for this application. This Action was mailed within the four months of the filing of the reply filed under 35 U.S.C. §132.

On June 30, 2009, Applicants paid the Issue Fee. This payment was received within three months of the mailing date of the Notice.

On September 22, 2009 the patent issued. The patent issued within four months of the paying the issue fee under 35 U.S.C. §151.

According to the provisions of 37 C.F.R. §1.702(b), Applicants are entitled to Patent Term Adjustment for the failure of the Office to issue the patent within three years after the date on which the application was filed. Under 37 C.F.R. §1.702(b)(1)-(5), Applicants are entitled to this adjustment for any time other than any time consumed by continued examination of the application requested by the applicant under section 132(b), beginning on the date on which a Request for Continued Examination was filed, January 11, 2008, and ending on the date the patent issues.

The amount of the Adjustment under 37 C.F.R. §1.702(b) is calculated from December 4, 2006 (*i.e.*, the day after the date that is three years from the date that the application was filed), through and including January 10, 2008, the day before the date the Request for Continued Examination was filed on January 11, 2008, subtracting only time legitimately attributable to applicant delay. Applicants submit that the Adjustment under 37 C.F.R. §1.702(b) is 403 days.

Applicants have calculated the Patent Term Adjustment based on 37 C.F.R. 1.702(a), 37 C.F.R. 1.702(b) and 37 C.F.R. 1.704 through the Issue date of the Patent. Applicants submit that an additional 403 days of Office delay should be included, under 37 C.F.R. 1.702(b), in calculating the total Patent Term Adjustment. Accordingly, the total calculation of Patent Term Adjustment is as follows: Office delay under 37 CFR 1.702(a) is 596 days; Office Delay under 37 CFR 1.702(b) is 403 days; and Applicant delay under 37 CFR 1.704(c) is: $92+92=184$ days; adjustment: $(596+403-184) = 815$ days.

Applicants respectfully request that the Patent Term Adjustment be increased from 412 days, as reported on the Determination of Patent Term Adjustment under 35 U.S.C. 154 (b), to **815 days**.

In addition to the foregoing, a Terminal Disclaimer was filed on September 5, 2008 directed to USSN 10/843,033, USSN 11/351,185 and USSN 11/364,964.

If the Office would like to discuss any aspect of this filing, the Office representative assigned to process this request is welcome to call the undersigned attorneys. Applicants believe no additional fees are due as the Office acknowledged the submission of the \$200.00 fee set forth in 37 C.F.R. §1.18(e) in the Decision mailed August 13, 2009 by the Office of Petitions. A copy of the Decision is attached. However, the Office is authorized to charge such fee, or credit any overpayment in fees to Deposit Account No. **50-0311**, Customer Number **30623**, Attorney Docket No. 25681-502 P.

Respectfully submitted,



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Date: November 20, 2009

Exhibit A

10/728,227	METHOD FOR DIAGNOSING DISEASES BASED ON LEVELS OF ANTI-GLYCAN ANTIBODIES	11-19-2009::12:49:49
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Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 10/728,227

Filing or 371(c) Date:	12-03-2003	USPTO Delay (PTO) Delay (days):	596
Issue Date of Patent:	09-22-2009	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	184
Post-Issue Petitions (days):	+0	Total PTA (days):	412
USPTO Adjustment(days):	+0	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
09-02-2009	PTA 36 Months		
09-22-2009	Patent Issue Date Used in PTA Calculation		
08-20-2009	Dispatch to FDC		
08-13-2009	Mail-Petition Decision - Dismissed		
08-13-2009	Petition Decision - Dismissed		
06-30-2009	Petition Entered		
07-01-2009	Application Is Considered Ready for Issue		
06-30-2009	Issue Fee Payment Verified		
06-30-2009	Issue Fee Payment Received		
04-01-2009	Response to Reasons for Allowance		
03-31-2009	Mail Notice of Allowance		
03-27-2009	Document Verification		
03-27-2009	Notice of Allowance Data Verification Completed		
03-27-2009	Case Docketed to Examiner in GAU		
03-26-2009	Examiner's Amendment Communication		
03-23-2009	Examiner Interview Summary Record (PTOL - 413)		
03-25-2009	Date Forwarded to Examiner		
03-18-2009	Response after Non-Final Action		
03-18-2009	Mail Examiner Interview Summary (PTOL - 413)		
03-12-2009	Examiner Interview Summary Record (PTOL - 413)		
12-23-2008	Mail Non-Final Rejection		
12-22-2008	Non-Final Rejection		
10-22-2008	Paralegal TD Accepted		
09-05-2008	Terminal Disclaimer Filed		
09-05-2008	Miscellaneous Incoming Letter		
10-17-2008	Date Forwarded to Examiner		
09-05-2008	Response after Non-Final Action		92
09-05-2008	Request for Extension of Time - Granted		⬆
07-09-2008	Mail Examiner Interview Summary (PTOL - 413)		⬆
06-26-2008	Examiner Interview Summary Record (PTOL - 413)		⬆
03-05-2008	Mail Non-Final Rejection		⬆

02-28-2008	Non-Final Rejection	
01-11-2008	Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received	
01-29-2008	Date Forwarded to Examiner	
01-29-2008	Date Forwarded to Examiner	
01-11-2008	Request for Continued Examination (RCE)	92
01-29-2008	DISPOSAL FOR A RCE/CPA/129 (express abandonment if CPA)	⬆
01-11-2008	Request for Extension of Time - Granted	⬆
01-11-2008	Workflow - Request for RCE - Begin	⬆
07-11-2007	Mail Final Rejection (PTOL - 326)	⬆
07-09-2007	Final Rejection	
04-29-2007	Date Forwarded to Examiner	
04-05-2007	Response after Non-Final Action	
01-05-2007	Mail Non-Final Rejection	
12-29-2006	Non-Final Rejection	
10-04-2005	Information Disclosure Statement considered	
03-17-2006	Information Disclosure Statement considered	
11-01-2006	Date Forwarded to Examiner	
10-20-2006	Response to Election / Restriction Filed	
09-22-2006	Mail Restriction Requirement	596
09-18-2006	Requirement for Restriction / Election	⬆
03-17-2006	Reference capture on IDS	⬆
03-17-2006	Information Disclosure Statement (IDS) Filed	⬆
03-17-2006	Information Disclosure Statement (IDS) Filed	⬆
10-04-2005	Reference capture on IDS	⬆
10-04-2005	Information Disclosure Statement (IDS) Filed	⬆
10-04-2005	Information Disclosure Statement (IDS) Filed	⬆
09-27-2004	IFW TSS Processing by Tech Center Complete	⬆
09-27-2004	Case Docketed to Examiner in GAU	⬆
06-18-2004	New or Additional Drawing Filed	⬆
06-18-2004	Preliminary Amendment	⬆
07-13-2004	Application Return from OIPE	⬆
07-13-2004	Application Return TO OIPE	⬆
07-13-2004	Application Dispatched from OIPE	⬆
07-13-2004	Application Is Now Complete	⬆
06-18-2004	Additional Application Filing Fees	⬆
06-18-2004	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applicant	⬆
06-18-2004	Applicant has submitted new drawings to correct Corrected Papers problems	⬆
03-18-2004	Notice Mailed--Application Incomplete--Filing Date Assigned	⬆
03-01-2004	Cleared by L&R (LARS)	⬆

02-11-2004	Referred to Level 2 (LARS) by OIPE CSR	⬆
12-28-2003	IFW Scan & PACR Auto Security Review	⬆
12-03-2003	Initial Exam Team nn	⬆

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United States Patent and Trademark Office
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OFFICE OF PETITIONS

MINTZ, LEVIN, COHN, FERRIS,
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BOSTON MA 02111

In re Application of :
Dotan, et al. :
Application No. 10/728,227 : ON APPLICATION FOR
Filed: December 3, 2003 : PATENT TERM ADJUSTMENT
Atty Docket No. 25681-502-P :

This is in response to the REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b) filed June 30, 2009. Applicant submits that the correct patent term adjustment to be indicated on the patent is eight hundred fifteen (815) days, not four hundred twelve (412) days as calculated by the Office as of the mailing of the initial determination of patent term adjustment. Applicant requests this correction solely on the basis that the Office will take in excess of three years to issue this patent.

As the instant application for patent term adjustment requests reconsideration of the patent term adjustment as it relates to the Office's failure to issue the patent within 3 years of the filing date, the application for patent term adjustment under 37 CFR 1.705(b) is DISMISSED as PREMATURE.

Knowledge of the actual date the patent issues is required to calculate the amount, if any, of additional patent term patentee is entitled to for Office failure to issue the patent within 3 years. See § 1.702(b). (This is true even where a request for continued examination (RCE) was filed). The computer will not undertake the § 1.702(b) calculation until the actual date of issuance of the patent has been determined. Likewise, the computer will not calculate any further Office delay under § 1.702(a)(4) or applicant delay under § 1.704(c)(10) until the actual date of issuance of the patent has been determined. As such, the Office can not make a determination on the correctness of the patent term adjustment until the patent has issued.

Requesting reconsideration of the patent term adjustment to be indicated on the patent under 37 CFR 1.705(b) based on the initial determination of patent term adjustment and a projected issuance date of the patent (or even the filing date of the request for continued examination) is premature. Accordingly, it is appropriate to dismiss as premature such a request.

Rather than file an application for patent term adjustment under 37 CFR 1.705(b) contesting the 37 CFR 1.702(b) calculation at the time of the mailing of the notice of allowance, applicant is advised that they may wait until the time of the issuance of the patent and file a request for reconsideration of the patent term adjustment pursuant to 37 CFR 1.705(d). As the USPTO does not calculate the amount of time earned pursuant to 37 CFR 1.702(b) until the time of the issuance of the patent, the Office will consider any request for reconsideration of the patent term adjustment due to an error in the calculation of 37 CFR 1.702(b) to be timely if the request for reconsideration is filed within two months of the issuance of the patent. However, as to all other bases for contesting the initial determination of patent term adjustment received with the notice of allowance, applicant must timely file an application for patent term adjustment prior to the payment of the issue fee¹.

It is acknowledged that applicant is correct that any period of adjustment will be entered in light of 35 U.S.C. 154(B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY, which provides that:

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including -

¹ For example, if applicant disputes both the calculation of patent term adjustment under 37 CFR 1.702(a)(1) for Office failure to mail a first Office action or notice of allowance not later than fourteen months after the date on which the application was filed and under 37 CFR 1.702(b) for Office failure to issue a patent within three years of the actual filing date of the application, then applicant must still timely file an application for patent term adjustment prior to the payment of the issue fee to contest the calculation of Office delay in issuing a first Office action or notice of allowance. See 37 CFR 1.705(b) and 35 U.S.C. 154(b)(3)(B). A dispute as to the calculation of the §1.702(a)(1) period raised on request for reconsideration of patent term adjustment under 37 CFR 1.705(d) will be dismissed as untimely filed.

(i) any time consumed by continued examination of the application requested by the applicant under section 132(b);

It is noted that a Request for Continued Examination (RCE) was filed in this application on January 11, 2008.

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e) for consideration of the application for patent term adjustment under 37 CFR 1.705(b).

Any request for reconsideration of the patent term adjustment indicated on the patent must be timely filed within 2 months after issuance pursuant to 37 CFR 1.705(d) and must include payment of the required fee under 37 CFR 1.18(e).

The Office of Data Management has been advised of this decision. This application is being referred to the Office of Data Management for issuance of the patent.

Telephone inquiries specific to this decision should be directed to Kenya A. McLaughlin, Petitions Attorney, at (571) 272-3222.

Christina Tartera Donnell

Christina Tartera Donnell
Senior Petitions Attorney
Office of Petitions